JAN 0 2 2002

K003689

510(k) Summary

Prepared: November 7, 2000

Submitter:

Company Name:	Canon USA, Inc. (U.S. designated agent for Canon Inc.)
Company Address:	One Canon Plaza Lake Success, NY 11042
Contact Person:	Sheila Driscoll, Senior Product Safety Engineer
Phone Number:	(516) 328-5602
Fax Number:	(516) 328-5169

Proposed Device:

Reason For 510(k):	New Model
Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-31
Classification Name:	90MQB, Solid State X-ray Imager
FDA 510(k) #:	To be assigned

Predicate Device:

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-11
Classification Name:	90MQB, Solid State X-ray Imager
FDA 510(k) #:	K981556

Description Of Device:

The Canon X-ray digital camera model CXDI-31 is used to directly capture and convert conventional projection X-ray images to digital images. A sub-sampled image can be displayed on a preview monitor for viewing. The diagnostic image can be transmitted through a DICOM compatible digital network for printing. The device provides digital image capture for conventional film/screen radiographic examinations.

The Canon X-ray Digital Camera CXDI-31 is substantually equivalent to the Canon X-ray Digital Camera CXDI-11. It differs from the CXDI-11 in that the CXDI-11 is connected to an upright stand, while the CXDI-31 is a portable unit and can be placed on top of radiology tables etc.

Intended Use:

Canon X-ray digital camera CXDI-31 provides digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

Technical Characteristics:

Please refer to the attached COMPARISON CHART.

Table of comparison

Item		CXDI-11	CXDI-31
Intended Use		Provide diagnostic images for general radiography with upright system	Provide diagnostic images for general radiography
Design		Digital acquisition, electronic processing	Same
Energy Uses		Receives x-radiation generated by external x-ray generator	Same
Materials	X-ray Absorber	Fluorescent screen ($Gd_2O_2S:TB^{3+}$) Visible emission peak: 545nm	Same
	Sensing Means	Amorphous Silicon W/TFT Array Detection peak: 540- 620nm	Same
Anatomical Sites		General radiography	Same
Target Population		General population	Same
Physical Safety		Minimize exposure to x-radiation	Same
Compliance with Standard		Complies with IEC 601-1-2	Same
Biocompatibility		N/A	N/A
Performance		After digital processing (optimize the gray-scale)	Same
Labeling		Approved 510(K)	See attachment labeling
Pixel		2688×2688 pixels (7,200,000 pixels)	2256×2878 pixels (6,490,000 pixels)
Image size		43cm×43cm	22.6cm×28.8cm
Pixel pitch		160μm	100μm
MTF		MTF@2lp/mm 42%	MTF@2lp/mm 42%
Dynamic Range		Dynamic range: approximately 4 digit (linear A/D : 14bit) (output data : 12bit)	Same
Grid		Moving grid	Stationary grid (removable)
Sensor Unit		552 x 598 x 231mm	324x 327 x 20mm

Item	CXDI-11	CXDI-31
Power Supply	580 x 489 x 275mm	Same
Control PC	483.5 x 594 x 300mm	Same
Operation Unit	298 x 209.5 x 130mm	Same
Card Reader	50 x 180 x 39mm	Same
Stand	900 x 475 x 2100mm	N/A
Table	N/A	N/A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 2 2002

Ms. Sheila J. Driscoll
Senior Product Safety Engineer
CANON U.S.A., Inc.
One Canon Plaza
LAKE SUCCESS NY 11042

Re: K003689
Trade/Device Name: Canon X-Ray Digital Camera
Model CXDI-31
Regulation Number: 21 CFR 892.1630
Regulation Name: Electrostatic x-ray imaging system
Regulatory Class: II
Product Code: 90 MQB
Dated: October 19, 2001
Received: October 22, 2001

Dear Ms. Driscoll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

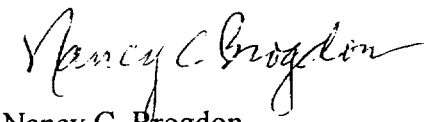
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications Statement

510(K)Number(if known): K003689

Device Name: _____

Indications for Use:

CANON X-RAY DIGITAL CAMERA CXDI-31 provides digital image capture for conventional film/screen radiographic examinations.
The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHERT PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K003689